



# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P2435PC00		<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/NO2004/000204		International filing date (day/month/year) 02.07.2004	Priority date (day/month/year) 04.07.2003	
International Patent Classification (IPC) or national classification and IPC A61K35/74				
Applicant THIA MEDICA AS et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 21.12.2004		Date of completion of this report 27.10.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Friederich, M Telephone No. +49 89 2399-7860 		

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/NO2004/000204

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ **Description, Pages**

1-24 as published

**Claims, Numbers**

1-21 as published

**Drawings, Sheets**

1/4-4/4 as published

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/NO2004/000204

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	3,7-21
	No: Claims	1,2,4-6
Inventive step (IS)	Yes: Claims	10-13,15
	No: Claims	3,7-9,14,16-21
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/NO2004/000204

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

The international search report refers to A-documents only. Therefore the following documents D1 and D2 are cited by examiner's knowledge. Copies of the documents are appended hereto.

D1: JP2001302523 (Patent abstracts of Japan)

D2: JP2002212083 (Patent abstracts of Japan)

**Art. 6** As already stated by the international searching authority, **claims 3-5** should be directed to specified pathological conditions (diseases).  
Present claim 9 refers to all preceding claims. The treatment or prevention of the diseases cited in **claim 1** in oysters or other animals cited in **claim 9** is unclear.

**Art. 33(2)** The above mentioned lack of clarity notwithstanding, the present application does not meet the requirements of Article 33(2) PCT, because the subject-matter of **claims 1, 2 and 4-6** does not appear to be new in the sense of Article 33(2) PCT.

D1 discloses the use of Lactobacillus and/or Streptococcus strains for the treatment/prophylaxis of arteriosclerosis.

Since present **claims 1, 2 and 4-6** are neither restricted to the microorganisms cited in claims 10-13 of the present application nor to a purified protein fraction (see claim 15), the subject-matter of **said claims 1, 2 and 4-6** is not considered to be new (Article 33(2) PCT).

A similar reasoning applies for the use of the Saccharomyces strains disclosed in D2.

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

**PCT/NO2004/000204**

**Art. 33(3)** An inventive step in the sense of Art. 33(3) PCT could be acknowledged for the claimed use of the specific protein fractions obtained according to the examples of the present application (claims 10-13 and 15).

**Art. 33(4)** The subject-matter of **claims 1-21** is considered to be industrially applicable in the sense of Art. 33(4) PCT.